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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/650,038	08/28/2003	Michael Haisch	0902-005	6948

42015 7590 09/23/2005

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EXAMINER
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LAVARIAS, ARNEL C

ART UNIT	PAPER NUMBER
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2872

DATE MAILED: 09/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/650,038

Applicant(s)

HAISCH ET AL.

Examiner

Arnel C. Lavarias

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 7/26/05, 2/25/05, 9/17/04, 2/2/04, 8/28/03.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 8-11, 30-32, 35 and 40-52 is/are pending in the application.
- 4a) Of the above claim(s) 41, 42 and 44-52 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 8-11, 30-32, 35, 40, 43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 August 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
  - 2) ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 9/17/04, 2/2/04.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Response to Amendment***

1. The amendments to the claims in the submission dated 2/25/05 are acknowledged and accepted.
2. The declaration under 37 CFR 1.132 filed 2/9/04 is acknowledged. However, it is insufficient to overcome the rejection of Claim 40 based upon 35 U.S.C. 102(a) as set forth below because: 35 U.S.C. 102(a) states that “A person shall be entitled to a patent unless the invention was known or used *by others* in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.” With respect to the subject matter recited in Claim 40, the inventive entity for the instant application is Michael Haisch, Christoph Hauger, Gerhard Gaida, and Andreas Raabe (as amended, see below). However, the inventive entity attributed to the subject matter disclosed on Page 133 in the paragraph under the heading “Technique for ICG Video Angiography” (See the article, A. Raabe et al., “Near-Infrared Indocyanine Green Video Angiography: A New Method for Intraoperative Assessment of Vascular Flow”, Neuro Surgery, vol. 52, no. 1, January 2003, pp. 132-139.) is Andreas Raabe, which is different than the inventive entity of the instant application.

### ***Election/Restrictions***

3. Applicant’s election of Group I (Claims 9-11, 30-32) in the reply filed on 7/26/05 is acknowledged. Because applicant did not distinctly and specifically point out the

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supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

4. Claims 41-42, 44-52 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 7/26/05.

#### ***Inventorship***

5. In view of the papers filed 7/26/05, the inventorship in this nonprovisional application has been changed by the deletion of inventors Hartmut Wolf, Joachim Hug, and Brigita Schwarz.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of Office records to reflect the inventorship as corrected.

#### ***Priority***

6. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

#### ***Drawings***

7. The drawings were received on 8/28/03. These drawings are objected to for the following reason(s) as set forth below.

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8. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description:

Figure 3- Reference numeral S7.

Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

9. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description:

Figure 4- Reference numerals 24, 89, 550.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are

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not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

10. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because the following reference characters have been used to designate multiple parts:

Reference numerals 18, 29, 35, 39, 31, 37, 16, 14, 91, 90, 9, 11, 79, 81, 3, 77, 73, 25, 21, 23, 69, 71, 47, 67, 45, 65, 55, 49, 51, 53, 41, 43, 57, 63.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Specification***

11. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to *a single paragraph on a separate sheet within the range of 50 to 150 words*. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the

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disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. *It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.*

12. The abstract of the disclosure is objected to because of the following informalities:

Abstract is too long.

Abstract, line 8- delete 'are provided'.

Abstract, line 27- delete '(figure 1)'

Correction is required. See MPEP § 608.01(b).

13. The disclosure is objected to because of the following informalities:

Page 11, line 25- 'the' should read 'The'

Page 16, line 12- 'splitted' should read 'split'

Page 20, line 27- '84' should read '85'

Page 31, lines 26, 28- '250' should read '205'

Page 31, line 31- '250' should read '200'

Page 32, line 23- '255' should read '55'.

Appropriate correction is required.

### ***Claim Objections***

14. Claims 8-11, 30-32, 43 are objected to because of the following informalities:

Claim 8 recites the limitation "the user" in line 15. There is insufficient antecedent basis for this limitation in the claim. Claims 9-11, 30-32, 43 are dependent on Claim 8, and hence inherit the deficiencies of Claim 8.

Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

16. Claims 8, 30-31, 35, 43, as best understood, are rejected under 35 U.S.C. 102(b) as being anticipated by Kitajima (U.S. Patent No. 5865829), of record.

Kitajima discloses a microscopy system for visualizing a fluorescence of a fluorescent substance in an object to be inspected (See for example Figures 1-4, 7-8, 10), wherein the microscopy system comprises a microscopy optics having a first beam path (See light paths passing from element 13 to elements 91, 91' via 80, 80', then to 93, 93' and 2 in Figure 8; col. 8, line 53-col. 14, line 67) for optically imaging an object region onto a light detecting component of a first camera (See 91, 91' in Figure 8) for generating first image data representing images of the object region with light including wavelengths of a first wavelength range comprising a fluorescent emission wavelength of the fluorescent substance, and a second beam path (See light paths passing from element 13 to element 2



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via 80, 80' and 35, 45 in Figure 8; col. 8, line 53-col. 14, line 67) for providing a magnified first representation of the object region, wherein the first representation represents images of the object regions with light including wavelengths of a second wavelength range comprising at least visible light; an image memory (See 160, 161 in Figure 8) for storing a set of first image data detected by the first camera during at least a time duration; and a display system (See 93, 93' in Figure 8) for displaying a sequence of second representations generated from at least a subset of first image data, wherein the sequence of second representations is displayed in superposition with the first representation for observation by the user (See also Figure 12). Kitajima additionally discloses the first beam path comprising at least one ocular for representing the images (See 35, 45 in Figure 8); the display system being configured to superimpose the second representation with the first beam path directed to the ocular (See Figure 8; col. 53-col. 14, line 67); and the fluorescent substance comprises indocyanine green (See col. 12, lines 1-2). Kitajima additionally discloses a microscopy method (See Figures 8, 12; col. 8, line 53-col. 14, line 67) for visualizing a fluorescence of an object to be inspected, the method comprising displaying a magnified first representation of the object for observation by a user, wherein the fluorescence of the object is substantially not visible in the first representation; recording a series of fluorescence light images of the object during a time duration; and displaying the recorded series of fluorescent light images of the object after the time period has lapsed (it is noted that there is an inherent time delay between recording the images on the camera and displaying these images on the display

system) such that the series of fluorescent light images is visible for the user and superimposed with the magnified first representation of the object.

17. Claim 40 is rejected under 35 U.S.C. 102(a) as being anticipated by Raabe et al. (A. Raabe, J. Beck, R. Gerlach, M. Zimmermann, V. Seifert, "Near-Infrared Indocyanine Green Video Angiography: A New Method for Intraoperative Assessment of Vascular Flow", Neuro Surgery, vol. 52, no. 1, January 2003, pp. 132-139.), of record.

Raabe et al. discloses a method of treating an aneurysm of a patient (See in particular Pages 133-134; Table 1), the method comprising clipping the aneurysm; injecting indocyanine green into the patient; generating at least one fluorescence image of at least one artery adjacent to the clipped aneurysm; and assessing vascular blood flow of the at least one artery based on the at least one fluorescence image.

***Claim Rejections - 35 USC § 103***

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

19. Claim 9, as best understood, is rejected under 35 U.S.C. 103(a) as being unpatentable over Kitajima.

Kitajima discloses the invention as set forth above in Claim 8, but does not explicitly disclose the display system being configured for repeatedly displaying the series of second representations. However, since Kitajima discloses that the series of image data

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are specifically stored in image memory (See 160, 161 in Figure 8) controllable via controller 66, it would have been readily evident and obvious to one having ordinary skill in the art to play back the stored image data in the image memory one or more times, as well as perform any number of other image processing functions on the image data stored in the image memory. One would have done this to simplify reviewing series of complex images without having to memorize or recall from one's memory, thus reducing mistakes.

20. Claims 10-11, as best understood, is rejected under 35 U.S.C. 103(a) as being unpatentable over Kitajima in view of Furusawa et al. (U.S. Patent No. 6371908), of record.

Kitajima discloses the invention as set forth above in Claim 8, except for the controller configured to select the subset from the set of first image data based on intensities of the images represented by the first data of the first set. However, Furusawa et al. teaches a conventional color observation system for use in an optical imaging system (See Figures 1-4), such as an endoscope, wherein fluorescence image data recorded from the CCD camera (See 17 in Figure 1) is sent to a video processor (See 13 in Figure 1). The video processor is configured to select a subset from the image data based on differences in intensities (particularly with respect to a baseline level) of the images in the image data (See Figures 5-14; col. 7, line 32-col. 11, line 59), and display a composite visible/fluorescence image. Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have the controller of Kitajima be configured to select the subset from the set of first image data based on intensities of the

images represented by the first data of the first set, as taught by Furusawa et al., simplify detection and identification of abnormal conditions of the observation object in the composite images.

21. Claim 32, as best understood, is rejected under 35 U.S.C. 103(a) as being unpatentable over Kitajima in view of Imaizumi et al. (JP 10325798A).

Kitajima discloses the invention as set forth above in Claim 8, except for the first beam path comprising at least one light detecting component of a second camera for generating second image data representing images of the object region with visible light. However, Imaizumi et al. discloses a conventional microscope apparatus (See for example Figure 1), including a first beam path (See light paths passing from element 2 to element 63, then to 70, 72, 71 in Figure 1) for optically imaging an object region onto a light detecting component of a first camera (See 71 in Figure 1) for generating first image data representing images of the object region with light including wavelengths of a first wavelength range comprising a fluorescent emission wavelength of the fluorescent substance, and a second beam path (See light paths passing from element 2 to element 64 in Figure 1) for providing a magnified first representation of the object region, wherein the first representation represents images of the object regions with light including wavelengths of a second wavelength range comprising at least visible light. In addition, the first beam path also includes a light detecting component of a second camera for generating second image data representing images of the object region with visible light (See 72 in Figure 1). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have the first path of the microscope

system of Kitajima further include at least one light detecting component of a second camera for generating second image data representing images of the object region with visible light, as taught by Imaizumi et al., for the purpose of providing simultaneous observation and storage of both fluorescence and visible light image data, both of which may be played back at a later time.

22. Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chari et al. (WO01/22870A1) in view of Ohishi et al. (U.S. Patent No. 6721590).

Chari et al. discloses a method of treating an aneurysm of a patient (See Figure 1; Page 5, line 31-Page 6, line 4; Page 7, lines 5-27; Page 8, line 28-Page 11, line 10), the method comprising administering a therapy to an aneurysm; injecting indocyanine green into the patient; generating at least one fluorescence image of at least one artery adjacent to the clipped aneurysm (It is noted that the injection and generation steps may be performed before, as well as after, the administration of the therapy to the aneurysm, See Page 7, lines 5-27); and assessing vascular blood flow of the at least one artery based on the at least one fluorescence image. Chari et al. lacks the step of administering a therapy to an aneurism including clipping the aneurysm. However, Ohishi et al. teaches various therapeutic methods of aneurysms, including clipping and insertion of a coil-like occluding material into the aneurysm (See col. 1, line 6-28). These therapeutic methods may be done in conjunction with fluorescence imaging techniques (See Figures 1, 3-4). Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have the step of administering a therapy to an aneurysm, as disclosed by Chari et al., include clipping the aneurysm, as taught by Ohishi et al., for the

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purpose of preventing blood from flowing into the aneurysm, which may burst due to increased blood pressure and cause injury or death.

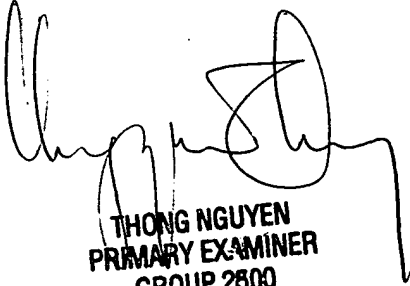
*Conclusion*

23. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arnel C. Lavarias whose telephone number is 571-272-2315. The examiner can normally be reached on M-F 9:30 AM - 6 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Drew Dunn can be reached on 571-272-2312. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Arnel C. Lavarias  
9/19/05

  
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